



**HEALTH AND HUMAN SERVICES  
U.S. FOOD AND DRUG ADMINISTRATION**

CFN#: 1125605

HF1-35



M3471n

**Baltimore District Office  
900 Madison Avenue  
Baltimore, MD 21201  
410-962-3396**

February 11, 2000

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Ms. Roberta Allen, President  
Individual Monitoring Systems, Inc.  
1507 Ritchie Highway, Suite #103  
Arnold, Maryland 21012

Dear Ms. Allen:

A Food and Drug Administration (FDA) inspection of your establishment located in Baltimore, Maryland conducted January 18-24, 2000, determined that you manufacture electroencephalographs. Electroencephalographs are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation, are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to establish a quality policy.
- Failure to establish and implement management review procedures and to document quality system reviews.
- Failure to establish and implement quality audit procedures and to conduct quality audits.
- Failure to establish a quality plan which defines the quality practices, resources, and activities relevant to devices designed and manufactured at your facility.
- Failure to establish procedures for identifying training needs and to ensure that all personnel are adequately trained to perform their assigned responsibilities.
- Failure to establish and maintain procedures for controlling changes to a specification, method, process or procedure.

- Failure to validate computer software for its intended use. For example, your firm has not validated the software used to perform sensitivity calibration of the ActiTrac device.
- Failure to establish and maintain procedures to ensure that all inspection, measuring, and test equipment, including mechanical, automated, and electronic inspection and test equipment, is suitable for its intended purposes and capable of producing valid results. For example, there were no calibration procedures or calibration records for the oscilloscope used to monitor the circuit board shaker table.
- Failure to establish and maintain procedures for implementing corrective and preventive action. For example, no investigation was conducted to determine the cause of failure for 14 incoming circuit boards, and no action was implemented to correct and prevent the recurrence of these failures.
- Failure to analyze complaints to identify existing and potential causes of nonconforming product.
- Failure to maintain a device history record for each unit manufactured. For example, there was no device history record available for ActiTrac Serial #13970 distributed on 10/15/99.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems related problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning devices so that they may take this information into account when awarding contracts. Additionally, no pre-market submissions for devices to which the QSR deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Product for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct any manufacturing or quality systems deviations. Failure to do so may be identified in a comprehensive follow-up inspection, and may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge receipt of your written responses dated January 24, 2000 and February 4, 2000 concerning our investigator's observations noted on form FDA-483. Until such time as the corrective actions promised in your letter of February 4, 2000 are completed, your ActiTrac device is in violation of the Act. Please advise this office in writing within 15 working days of receipt of this letter of your progress towards correcting these violations.

Ms. Roberta Allen  
February 11, 2000  
Page 3

Correspondence concerning this matter should be sent to David J. Gallant, Compliance Officer, U.S. Food & Drug Administration, 900 Madison Avenue, Baltimore, MD 21201. Mr. Gallant can be reached via telephone at (410) 962-3590, extension 140.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lee Bowers', with a long horizontal flourish extending to the right.

Lee Bowers  
Director, Baltimore District

cc: Dr. David T. Krausman, Vice President & CEO  
Individual Monitoring Systems, Inc.  
1055 Taylor Avenue, Suite #300  
Baltimore, MD 21286